



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,768	10/02/2000	Fang Dong	FORS-04766	4984

23535 7590 06/12/2002

MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER

GUNTER, DAVID R

ART UNIT PAPER NUMBER

1634

DATE MAILED: 06/12/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/676,768

Applicant(s)

DONG ET AL.

Examiner

David Gunter

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The examiner acknowledges the applicant's claim to priority for the instant application as a continuation of application 08/851,588, filed 05/05/1997
2. The examiner notes that both the Power of Attorney by Assignee and the Declaration of Small Entity Status are not signed.

Specification

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1634

4. Claims 16 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantially" in claims 16 and 23 is a relative term that renders the claim indefinite. Page 13, lines 28-30 of the specification states that "while it is not required that absolutely no formation of a first probe/second folded target complex occurs, very little of this complex is formed." This definition in the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The applicant should either define the hybridization conditions under which the method is to be performed and set limits for the acceptable level of hybridization for the first probe/second folded target complex, or remove the word "substantially" from the claims.

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 15-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,210,880. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 15 of the instant application recites a method in which two folded nucleic acid targets are combined with two oligonucleotide probes to form a series of probe/folded target complexes. The resulting complexes are brought into contact with a solid support containing four "testing zones" which are capable of immobilizing the oligonucleotide probes. Claims 16-19 of the instant application recite further limitations on the nature of the interaction between the probes and the folded targets, and the nature of the nucleic acids to be used as probes and targets.

Claim 1 of USPN '880 recites a method for capturing bridging oligonucleotides by combining two folded nucleic acid targets with two oligonucleotide probes to form a series of probe/folded target complexes. The resulting complexes are brought into contact with a solid support containing four "capture zones" which are capable of immobilizing the oligonucleotide probes. Claims 2-5 of USPN '880 recite further limitations on the nature of the interaction between the probes and the folded targets, and the nature of the nucleic acids to be used as probes and targets.

Based on the description of the inventions recited in Claims 15-19 of the instant application and Claims 1-5 of USPN '880, it would have been obvious to one of ordinary skill in the art that the "testing zones" of the instant application perform the same function as the "capture zones" of USPN '880. Claims 1-5 of USPN '880 recite the additional limitation that the oligonucleotide probes used for the method are "bridging oligonucleotides." However, despite the minor differences in terminology and the additional limitation found in USPN '880, it would have been obvious to one of ordinary skill in the art that the probes of Claims 15-19 of the instant application perform the same function as the bridging oligonucleotides of Claims 1-5 of USPN '880. The further limitations recited by Claims 16-19 of the instant application are identical to the limitations recited in claims 2-5 of USPN '880 with the exception that the oligonucleotide probes are referred to simply as "probes" in the instant application and are referred to as "bridging oligonucleotides" in USPN '880. Because it would have been obvious to one of ordinary skill in the art that the oligonucleotide probes perform the same function, it would also have been obvious to one of ordinary skill in the art that the limitations recited in claims 16-19 of the instant application serve the same functions as the limitations recited in claims 2-5 of USPN '880.

6. Claims 20-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-13 of U.S. Patent No. '880. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 20 of the instant application recites a method in which two folded nucleic acid targets are brought into contact with a solid support. Two oligonucleotide probes are bound to two "testing zones" on the solid support and the folded nucleic acid targets are allowed to hybridize to the immobilized

Art Unit: 1634

probes. Claims 21-27 recite additional limitations regarding the location of the probes on the solid support, the nature of the interaction between the probes and the nucleic acid targets, and the nature of the nucleic acids to be used as probes and targets.

Claim 6 of USPN '880 recites a method for forming a probe/folded target complex in which two folded nucleic acid targets are brought into contact with a solid support. Two oligonucleotide probes are bound to two "testing zones" on the solid support and the folded nucleic acid targets are allowed to hybridize to the immobilized probes. Claims 7-13 recite additional limitations regarding the location of the probes on the solid support, the nature of the interaction between the probes and the nucleic acid targets, and the nature of the nucleic acids to be used as probes and targets. Based on the description of the invention recited in the Claims, it would have been obvious to one of ordinary skill in the art that the "testing zones" recited in Claims 20-27 of the instant application perform the same function as the "capture zones" recited in Claims 6-13 of USPN '880.

The language of claims 20-27 of the instant application and claims 6-13 of USPN '880 are nearly identical. The only differences between them are the use of "testing zones" and "capture zones" as described above, and that USPN '880 recites the additional limitation that the oligonucleotide probes used are "bridging oligonucleotides." As described above, it would have been obvious to one of ordinary skill in the art that the oligonucleotide probes of the instant application perform the same function as the bridging oligonucleotides of USPN '880, and that the testing zones of the instant application are functionally equivalent to the capture zones of USPN '880. Therefore it would also have been obvious to one of ordinary skill in the art that the

Art Unit: 1634

limitations recited in claims 16-19 of the instant application serve the same functions as the limitations recited in claims 2-5 of UPSN '880.

Provisional Obviousness-type Double Patenting

7. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-15 of co-pending Application No. 09/825,574. Claim 1 of the instant application recites a method of mixing a folded DNA target sequence with one or more complementary oligonucleotide probes. Claims 2-14 recite additional method steps for and limitations to the method of mixing the probes and folded DNA target.

Claim 1 of co-pending application 09/825,574 recites a method for determination of structure formation in nucleic acid targets comprising mixing a folded DNA target sequence with one or more bridging oligonucleotide probes complementary to the target. Claims 3-15 recite additional method steps for and limitations to the method of mixing the probes and folded DNA target.

Claim 1 of the instant application differs from Claim 1 of co-pending application '574 only in the fact that the co-pending application recites the additional limitation that the oligonucleotide probes are to be "bridging oligonucleotides." The additional method steps and limitations recited in claims 2-14 of the instant application are identical to those recited in claims 3-15 of co-pending application '574. As described above, it would have been obvious to one of ordinary skill in the art that the oligonucleotide probes of the instant application perform the same function as the bridging oligonucleotides of UPSN '880. Therefore, it would also be

obvious to one of ordinary skill in the art that the additional limitations recited by Claims 2-14 of the instant application serve the same functions as the limitations recited by Claims 3-15 of co-pending application '574.

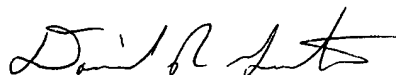
This is a provisional obviousness-type double patenting rejection.

8. No claims are allowed.

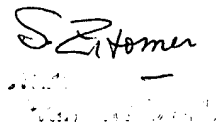
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701. The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9212 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.



David R. Gunter, DVM, PhD
May 24, 2002



S. Z. Y. Jones
Supervisor